

Akin Gump

STRAUSS HAUER & FELD LLP

CHARLES L. FRANKLIN

+1 202.887.4378/fax: +1 202.887.4288
clfranklin@akingump.com

January 29, 2014

Mr. Larry F. Gottesman
National Freedom of Information Officer
U.S. Environmental Protection Agency
Records, FOIA and Privacy Branch
1200 Pennsylvania Avenue, N.W. (2822T)
Washington, DC 20460

Re: Targeted Freedom of Information Act Request

Dear Mr. Gottesman:

Pursuant to Section 552 of the Administrative Procedure Act, 5 U.S.C. § 552, and 40 C.F.R. § 2, I am requesting copies of each and any final efficacy protocol relied upon by EPA in reviewing and accepting the efficacy data submitted by Ag-Chem Consulting, Cupron Scientific, or any other entity submitting an efficacy protocol or efficacy data on behalf of the products and labels registered under Reg No. 84542-10 (Cupron Anti-Fungal Fibers and Fabrics II”) and/or Reg. No. 84542-11 (“Cupron Anti-Fungal Fibers and Fabrics III”)(collectively, the Cupron Anti-Fungal Fiber and Fabric Registrations”), to support its approval of any one or more of the antimicrobial claims listed on the two stamped labels for the Cupron Anti-Fungal Fibers and Fabrics Registrations dated June 6, 2013 (enclosed as Exhibits A and B).

We understand that EPA may, from time to time, update or revise previously approved protocols prior to posting such documents on line for broader use as a public reference, either to address confidential business information (CBI) concerns or to update or revise EPA policy with respect to evolving policy. This request, however, is limited to the form of each aforementioned protocol as specifically relied upon at the time of the June 6, 2013 registration decisions. To the extent such protocols may contain confidential business information which may be entitled to confidential treatment, or which otherwise may be exempt from disclosure under FOIA, we request a redacted version of the original protocol documents rather than a revised and reformatted document.

We agree to pay the reasonable charges incurred photocopying the requested documents, and will accept production of the requested documents in electronic or hard-copy form, with a preference for the format which can be produced most quickly.

Mr. Larry F. Gottesman
January 29, 2014
Page 2

Please do not hesitate to contact me at (202) 887-4378 should you have any questions.

Sincerely,

A handwritten signature in black ink, appearing to read "Charles L. Franklin", with a long horizontal flourish extending to the right.

Charles L. Franklin
Attorney for PurThread Technologies, Inc.

Enclosures

cc: Emily Mitchell, Branch Chief, mitchell.emily@epa.gov (703-308-8583)
Mark Perry, perry.mark@epa.gov (703-308-8024)
Earl Ingram, ingram.earl@epa.gov (703) 305-5456
Devenchi Arnold, arnold.devenchi@epa.gov (703) 305-5698
Janet Bressant, bressant.janet@epa.gov (703) 305-6445

Exhibit A

84542-10

6/6/2013
1

1/5



U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Antimicrobials Division (7510P)
1200 Pennsylvania Avenue NW
Washington, D.C. 20460

EPA Reg. Number:

84542-10

Date of Issuance:

JUN 6 2013

Term of Issuance:

Conditional

Name of Pesticide Product:

**Cupron Anti-Fungal Fibers and
Fabrics II**

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration
(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Ag-Chem Consulting
Cupron Scientific
12208 Quinque Lane
Clifton, VA 20124

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act. Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

The application referred to above, submitted under the Federal Insecticide, Fungicide and Rodenticide Act, as amended is acceptable under FIFRA sec. 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product when the Agency requires all registrants of similar products to submit such data.
2. Submit a one-year study required to satisfy the storage stability and corrosion characteristics requirements (Guidelines 830.6317 and 830.6320). You have 18 months from the date of registration to provide these data.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. The next label printing of this product must use this labeling unless subsequent changes have been approved. You must submit one (1) copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and it's implementing regulation at 40 CFR 152.3.

Signature of Approving Official:

Stacey Briggs
Jacqueline Campbell
Product Manager Team 34
Regulatory Management Branch
Antimicrobials Division (7510P)

Date:

JUN 6 2013

Master Label containing

Sublabel 1. Complete Label

Sublabel 2. Hang Tag label

CUPRON ANTI-FUNGAL FIBERS AND FABRICS II

[Additional Brand Name: Cupron AntiFungal Pro Fibers]

Active Ingredient

Copper (I) oxide 2.6 %

Other Ingredients (Garment) 97.4 %

Total 100 %

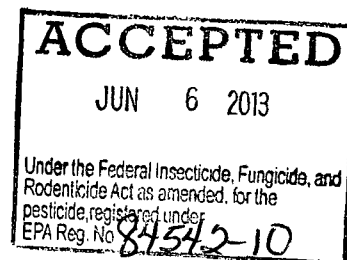
EPA Registration No. 84542-

EPA Establishment No *****

Made in the United States by Cupron Inc, Richmond, VA 23219

Distributed by*****

Net Contents*****



Cupron Anti Fungal Fibers and Fabrics II

Label Version 2

5/22/2013

Page 1 of 4

Sublabel I. Complete Label

Cupron Anti Fungal Fibers and Fabrics II

[When Additional Brand Name is used the statement Cupron enhanced fibers/fabric shown below is replaced with Cupron AntiFungal Pro Fibers]

-THIS TEXTILE (OR IDENTIFIED ACTIVE AREA) CONTAINS CUPRON ANTI-MICROBIAL TECHNOLOGY

Laboratory testing has shown that when cleaned regularly:

Cupron enhanced fibers/fabric will assist in reducing the spread of *T. mentagrophytes* (athlete's foot fungus).

Cupron enhanced fibers/fabric will [reduce, inhibit, suppress, kill] 99.9% of *T. mentagrophytes* (athlete's foot fungus) after 12 hours of contact with [sock, bathmats, shoe inserts].

Cupron enhanced fibers / fabric will inhibit the propagation and harboring of *T. mentagrophytes* on the [socks, bathmats, shoe inserts].

Cupron enhanced fibers / fabric will help to inhibit the growth of *T. mentagrophytes* the causative agent of athlete's foot on the [socks, bathmats, shoe inserts].

Cupron enhanced fibers / fabric will help to suppress the growth of *T. mentagrophytes* the fungus that is the causative agent of athlete's foot on the [socks, bathmats, shoe inserts].

Cupron enhanced fibers/fabric will [reduce, inhibit, suppress, kill] 99.9% of the *T. mentagrophytes* (athlete's foot fungus) on the [socks, bathmats, shoe inserts].

Cupron enhanced fibers / fabric will inhibit the growth of athlete's foot fungus on the [socks, bathmats, shoe inserts].

Cupron enhanced fibers/fabric reduce(s) the spread of *T. mentagrophytes*, athlete's foot fungus, on the surface of the sock.

Cupron enhanced fibers/fabric prevent(s) the growth of 99.9% of *T. mentagrophytes*, athlete's foot fungus, on the sock.

Cupron enhanced fibers / fabric will [reduce, inhibit, suppress, kill] 99.9% of *T. mentagrophytes*, athlete's foot fungus, on the [sock, bathmat, shoe inserts].

Cupron enhanced fibers/fabric significantly reduce(s) 99.9% of *T. mentagrophytes*, fungus that causes athlete's foot on the sock.

THIS PRODUCT IS EFFICACIOUS UP TO 20 MACHINE WASHINGS

Cupron Anti Fungal Fibers and Fabrics II

The use of this textile is a supplement to and not a substitute for standard infection control practices; users must continue to follow all current infection control practices, including those practices related to cleaning and sanitizing/disinfection of textiles. This textile has been shown to reduce microbial contamination, but it does not necessarily prevent cross contamination.

Active Ingredient	
Copper (I) Oxide	2.6 %
Other Ingredients (Garment)	97.4%
Total	100 %

EPA Registration No. 84543-

Made in the United States by Cupron Inc,
800 East Leigh Street, Richmond, VA 23219

EPA Establishment No *****

Distributed by*****

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

[The directions in bracketed text may be included in an insert. If so there will be a statement to see the insert for additional directions for use of the product]

This product will retain its antimicrobial properties for 20 washings if maintained in the following manner:

Machine Wash Regular (not compatible with silvercare machines)

Temperature Cold, Warm, or Hot (up to 176 degrees Fahrenheit)

Tumble dry hot (up to 347 degrees Fahrenheit) for up to 30 minutes

May use Clorox or similar bleach

Do not use fabric softener, or laundry detergent containing fabric softeners

Do not dry clean.

Cupron Anti Fungal Fibers and Fabrics II

[Cupron Anti Fungal Fibers and Fabrics II may be used in hospitals, other healthcare facilities, and various public, commercial and residential buildings for the uses listed below.]

TEXTILES ARE TO BE USED TO MAKE SOCKS, FOOTWEAR, SHOE INSERTS AND BATHMATS.

STORAGE AND DISPOSAL

Disposal: Discard in trash when fibers/fabric are worn out or after 20 washings. Do not reuse clothing for other purposes than as sold.

Sublabel 2: Hang Tag Label

CUPRON ANTI-FUNGAL FIBERS AND FABRICS II

Kills 99.9% of the following Fungus
after 12 hours of Exposure to the
Cupron Fibers and Fabrics:

(Trichophyton mentagrophytes)

(other tested fungi)

Active Ingredient
Copper (I) Oxide 2.6 %
EPA Reg. No

EPA Est No.

Dispose of garment in trash. Refer to
hang tag for more information

Exhibit B

84542-11

6/6/2013
1

1/5



U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Antimicrobials Division (7510P)
1200 Pennsylvania Avenue NW
Washington, D.C. 20460

EPA Reg. Number:

84542-11

Date of Issuance:

JUN 6 2013

Term of Issuance:

Conditional

Name of Pesticide Product:

**Cupron Anti-Fungal Fibers and
Fabrics III**

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration
(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Ag-Chem Consulting
Cupron Scientific
12208 Quinque Lane
Clifton, VA 20124

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act. Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

The application referred to above, submitted under the Federal Insecticide, Fungicide and Rodenticide Act, as amended is acceptable under FIFRA sec. 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product when the Agency requires all registrants of similar products to submit such data.
2. Submit a one-year study required to satisfy the storage stability and corrosion characteristics requirements (Guidelines 830.6317 and 830.6320). You have 18 months from the date of registration to provide these data.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. The next label printing of this product must use this labeling unless subsequent changes have been approved. You must submit one (1) copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Signature of Approving Official:

Stacey Bragg
Jacqueline Campbell
Product Manager Team 34
Regulatory Management Branch
Antimicrobials Division (7510P)

Date:

JUN 6 2013

Master Label containing
Sublabel 1. Complete Label
Sublabel 2. Hang Tag label

CUPRON ANTI-FUNGAL FIBERS AND FABRICS III

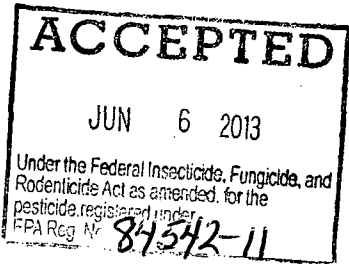
[Additional Brand Name: Cupron AntiFungal Fibers]

Active Ingredient	
Copper (I) oxide	1.95 %
Other Ingredients (Garment)	98.05.%
Total	100 %

EPA Registration No. 84542- EPA Establishment No *****

Made in the United States by Cupron Inc, Richmond, VA 23219

Distributed by***** Net Contents*****



Cupron Anti Fungal Fibers and Fabrics III

Sublabel I. Complete Label**Cupron Anti Fungal Fibers and Fabrics III**

[When Additional Brand Name is used the statement Cupron enhanced fibers/fabric shown below is replaced with Cupron AntiFungal Fibers]

-THIS TEXTILE (OR IDENTIFIED ACTIVE AREA) CONTAINS CUPRON ANTI-MICROBIAL TECHNOLOGY

Laboratory testing has shown that when cleaned regularly:

Cupron enhanced fibers/fabric will assist in reducing the spread of *T. mentagrophytes* (athlete's foot fungus).

Cupron enhanced fibers/fabric will [reduce, inhibit, suppress, kill] 99.9% of *T. mentagrophytes* (athlete's foot fungus) after 12 hours of contact with [sock, bathmats, shoe inserts].

Cupron enhanced fibers / fabric will inhibit the propagation and harboring of *T. mentagrophytes* on the [socks, bathmats, shoe inserts].

Cupron enhanced fibers / fabric will help to inhibit the growth of *T. mentagrophytes* the causative agent of athlete's foot on the [socks, bathmats, shoe inserts].

Cupron enhanced fibers / fabric will help to suppress the growth of *T. mentagrophytes* the fungus that is the causative agent of athlete's foot on the [socks, bathmats, shoe inserts].

Cupron enhanced fibers/fabric will [reduce, inhibit, suppress, kill] 99.9% of the *T. mentagrophytes* (athlete's foot fungus) on the [socks, bathmats, shoe inserts].

Cupron enhanced fibers / fabric will inhibit the growth of athlete's foot fungus on the [socks, bathmats, shoe inserts].

Cupron enhanced fibers/fabric reduce(s) the spread of *T. mentagrophytes*, athlete's foot fungus, on the surface of the sock.

Cupron enhanced fibers/fabric prevent(s) the growth of 99.9% of *T. mentagrophytes*, athlete's foot fungus, on the sock.

Cupron enhanced fibers / fabric will [reduce, inhibit, suppress, kill] 99.9% of *T. mentagrophytes*, athlete's foot fungus, on the [sock, bathmat, shoe inserts].

Cupron enhanced fibers/fabric significantly reduce(s) 99.9% of *T. mentagrophytes*, fungus that causes athlete's foot on the sock.

THIS PRODUCT IS EFFICACIOUS UP TO 20 MACHINE WASHINGS

Cupron Anti Fungal Fibers and Fabrics III

4/5

The use of this textile is a supplement to and not a substitute for standard infection control practices; users must continue to follow all current infection control practices, including those practices related to cleaning and sanitizing/disinfection of textiles. This textile has been shown to reduce microbial contamination, but it does not necessarily prevent cross contamination.

Active Ingredient	
Copper (I) Oxide	1.95%
Other Ingredients (Garment)	98.05%
Total	100 %

EPA Registration No. 84543-

Made in the United States by Cupron Inc,
800 East Leigh Street, Richmond, VA 23219

EPA Establishment No *****

Distributed by*****

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

[The directions in bracketed text may be included in an insert. If so there will be a statement to see the insert for additional directions for use of the product]

This product will retain its antimicrobial properties for 20 washings if maintained in the following manner:

Machine Wash Regular (not compatible with silvercare machines)

Temperature Cold, Warm, or Hot (up to 176 degrees Fahrenheit)

Tumble dry hot (up to 347 degrees Fahrenheit) for up to 30 minutes

May use Clorox or similar bleach

Do not use fabric softener, or laundry detergent containing fabric softeners

Do not dry clean.

Cupron Anti Fungal Fibers and Fabrics III

5/5

[Cupron Anti Fungal Fibers and Fabrics III may be used in hospitals, other healthcare facilities, and various public, commercial and residential buildings for the uses listed below.]

TEXTILES ARE TO BE USED TO MAKE SOCKS, FOOTWEAR, SHOE INSERTS AND BATHMATS.

STORAGE AND DISPOSAL

Disposal: Discard in trash when fibers/fabric are worn out or after 20 washings. Do not reuse clothing for other purposes than as sold.

Sublabel 2: Hang Tag Label

**CUPRON ANTI-FUNGAL FIBERS AND
FABRICS III**

Kills 99.9% of the following Fungus
after 12 hours of Exposure to the
Cupron Fibers and Fabrics:

(Trichophyton mentagrophytes)

(other tested fungi)

Active Ingredient

Copper (I) Oxide 1.95 %

EPA Reg. No

EPA Est No.

Dispose of garment in trash. Refer to
hang tag for more information